



Safety Data Sheet (SDS)

MATERIAL: Verapamil Hydrochloride Injection	SUPPLIER(S): Exela Pharma Sciences, LLC	SDS NO.: SDS-FP-004-00	ISSUE DATE: 04/22/2016
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Section 1 – Chemical Product and Company

Distributor:		Emergency Telephone:	(828) 448-8744
Exela Pharma Sciences, LLC 1245 Blowing Rock Blvd Lenoir, NC 28645 (828) 758-5474		Product Identifier:	Verapamil Hydrochloride Injection, USP
		Product Code:	51754-0203-1
		Common/Trade Name:	Verapamil Hydrochloride Injection, USP
Chemical Name:	C ₂₇ H ₃₈ N ₂ O ₄ · HCl	Chemical Family:	Calcium channel blocking agent
Product Use:	Pharmaceutical	Product Type:	Regulated Prescription Drug
Container Information:	Vials		

Section 2 – Hazards Identification

Primary Physical and Health Hazards:	This material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the cardiovascular system.
Routes of Entry:	Inhalation, eye/skin contact, or ingestion.
Signs and Symptoms of Exposure:	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. The following signs and symptoms have occurred in individuals: severe hypotension, cardiogenic shock, second-degree AV block, third-degree AV block, sick sinus syndrome, severe congestive heart failure. Treatment of overdosage should be supportive and individualized. Beta-adrenergic stimulation and/or parenteral administration of calcium injections may increase calcium ion flux across the slow channel, and have been effectively used in treatment of deliberate overdosage with oral verapamil hydrochloride. Verapamil Hydrochloride cannot be removed by hemodialysis. Clinically significant hypotensive reactions or high-degree AV block should be treated with vasopressor agents and/or cardiac pacing. Asystole should be handled by the usual measures including isoproterenol hydrochloride, other vasopressor agents, or cardiopulmonary resuscitation to treat acute overdosage with Verapamil Hydrochloride Injection.
Chemical Listed as Carcinogen:	NTP: No IARC: No OSHA: No
Medical Conditions Generally Aggravated by Exposure:	Hypersensitivity to any of the product's components.



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Section 3 – Composition / Information on Ingredients

Ingredient	Weight	CAS No.
Verapamil Hydrochloride	2.5 mg/mL, 5.0 mg / 2 mL	152-11-4
Sodium Chloride	8.5 mg/mL, 17 mg / 2 mL	7440-23-5
Hydrochloric Acid	pH to 4.9 (4.0 to 6.5)	7647-01-0
Water for Injection	N/A	7732-18-5

Section 4 – First Aid Measures

Eye Exposure:	Immediately flush with plenty of water. Seek medical attention.
Skin Exposure:	Immediately remove from skin with dry cloth followed by flushing with plenty of water for at least 15 minutes.
Ingestion:	Flush mouth out with water. Obtain medical attention immediately if ingested.
Injection:	See patient package insert in shipping carton for complete information.
Inhalation:	Move exposed subject to fresh air immediately. Obtain medical attention if ill effects occur.
Notes to Physician:	See patient package insert in shipping carton for complete information.



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Section 5 – Fire Fighting Measures

Flash Point:	Not established
Auto-ignition Temperature:	Not established
Flammable Limits in Air:	Lower %: Not established Upper %: Not established
Flammable Limits:	Not established
Extinguishing Media:	Use water or an ABC multi-purpose extinguisher for surrounding materials.
Special Fire Fighting Procedures:	Verapamil Hydrochloride solution thermally decomposes to form toxic vapors. Vapors can be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker Gear). Cool containers with water spray and use caution when approaching.

Section 6 – Accidental Release Measures

Spill:	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Release to Air:	If aerosolized, reduce exposure by ventilating area. Clean up spill immediately to prevent evaporation.
Release to Water:	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 – Handling and Storage

General Handling:	As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Use in well ventilated area.
Waste Disposal Method:	Dispose of in accordance with federal, state, and local regulations.
Storage Conditions:	Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature]. Follow instructions provided in packaging.



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Section 8 – Exposure Controls / Personal Protection

Respiratory Protection:	Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with P-100 / acid gas cartridges.
Eye Protection:	Wear ANSI approved chemical splash goggles or safety glasses.
Ventilation:	Local exhaust or general ventilation is recommended.
Skin Protection:	When administering this product to patients, wear nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for cleanup activities.
Other Protective Equipment:	Not required.
Additional Exposure Precautions:	Not required.

Exposure Limits

Compound	Issuer	Type	TWA
Verapamil Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Hydrochloric Acid	OSHA	PEL	5 ppm
	ACGIH	TLV	2 ppm
	-----	STEL	5 ppm
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE



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Section 9 – Physical and Chemical Properties

Physical State:	Aqueous Solution	Specific Gravity:	Approximately 1.0
Appearance and Odor:	Clear, colorless, odorless	Evaporation Point:	Not available
Boiling Point:	Above 212°F	Melting Point:	Not available
Vapor Pressure:	Not applicable	Solubility in Water:	Soluble
Vapor Density:	Not applicable	pH:	4.9
		Molecular Weight:	491.07

Section 10 – Stability and Reactivity

Stability:	Stable
Incompatibility (Materials to Avoid):	Reactive with oxidizing agents
Hazardous Decomposition:	Acrid and toxic vapors may be released by thermal decomposition.
Hazardous Polymerization:	Will not occur
Conditions to Avoid:	Avoid heat, light, and humidity. Keep away from flames, thermally decomposes to form toxic vapors.



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Section 11 – Toxicological Information

Primary Physical and Health Hazards:	This material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the cardiovascular system. The following signs and symptoms have occurred in individuals: severe hypotension, cardiogenic shock, second-degree AV block, third-degree AV block, sick sinus syndrome, severe congestive heart failure. Treatment of overdosage should be supportive and individualized. Beta-adrenergic stimulation and/or parenteral administration of calcium injections may increase calcium ion flux across the slow channel, and have been effectively used in treatment of deliberate overdosage with oral verapamil hydrochloride. Verapamil Hydrochloride cannot be removed by hemodialysis. Clinically significant hypotensive reactions or high-degree AV block should be treated with vasopressor agents and/or cardiac pacing. Asystole should be handled by the usual measures including isoproterenol hydrochloride, other vasopressor agents, or cardiopulmonary resuscitation to treat acute overdosage with Verapamil Hydrochloride Injection. See prescribing information.			
Acute Toxicity				
Component	Type	Route	Species	Dosage
Verapamil Hydrochloride	LD ₅₀	Oral	Rat	108 mg/kg
Verapamil Hydrochloride	LD ₅₀	Oral	Mouse	163 mg/kg
Verapamil Hydrochloride	LD ₅₀	Intravenous	Rat	16 mg/kg
Verapamil Hydrochloride	LD ₅₀	Intravenous	Mouse	5.8 mg/kg
Hydrochloric Acid	LD ₅₀	Oral	Rabbit	900 mg/kg
Hydrochloric Acid	LD ₅₀	Dermal	Mouse	3916 mg/kg

Section 12 – Ecological Information

No applicable ecological information found.



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Section 13 – Disposal Considerations

Waste Disposal:	Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.
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Section 14 – Transport Information

Regulatory Organizations:	DOT: Not Regulated
	ICAO/IATA: Not Regulated
	IMO: Not Regulated

Section 15 – Regulatory Information

Below is selected regulatory information chosen primarily for possible Exela Pharma Sciences usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA	Yes 8b inventory – Hydrochloric Acid
CERCLA	Yes – Hydrochloric Acid
SARA 302	Not on this list
SARA 313	Not on this list
OSHA Substance Specific	No
RTECS Number:	YV8320000 – Verapamil Hydrochloride MW4025000 – Hydrochloric Acid



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Section 16 – Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Exela Pharma Sciences, LLC
1245 Blowing Rock Blvd
Lenoir, NC 28645
(828) 758-5474



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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified



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NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)

SDS Approved by Jonathan E. Sterling, Vice President Quality and Regulatory Affairs

SDS Compliant to 29 CFR 1910.1200